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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,376	08/29/2003	Carl E. Fabian	0018-13	7325

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ERNEST D. BUFF  
ERNEST D. BUFF AND ASSOCIATES, LLC.  
231 SOMERVILLE ROAD  
BEDMINSTER, NJ 07921

EXAMINER
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BOGART, MICHAEL G

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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05/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

87

<b>Office Action Summary</b>	Application No. 10/650,376	Applicant(s) FABIAN, CARL E.	
	Examiner Michael G. Bogart	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 11, 13, 14 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11, 13, 14 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

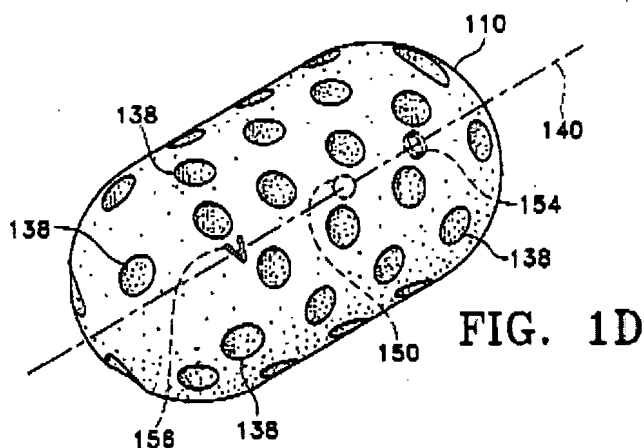
**DETAILED ACTION*****Claim Rejections - 35 USC § 103***

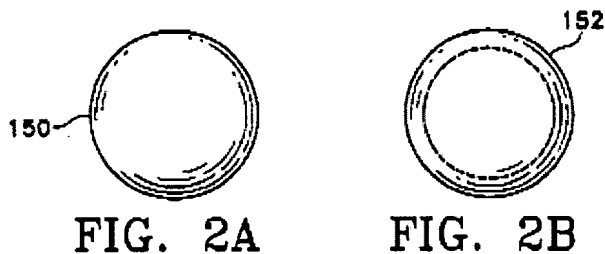
The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne *et al.* (US 6,371,904 B1; hereinafter "Sirimanne").

Regarding claims 1-7, Sirimanne teaches a surgical sponge (110) comprising three radiopaque markers (150, 154, 156), one of which (150) is a distinctive spherical shape, the markers (150, 154, 156) disposed in a substantially fixed relationship (col. 7, lines 44-60; col. 8, lines 6-67)(see figs. 1D, 2A and 2B, below).





Sirimanne does not disclose expressly the specific X-ray density or size of the markers.

Mere changes in size, weight or shape are not sufficient to patentably distinguish an invention over the prior art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.). See *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

In the instant case, it is well known in the art that increased density and size of a barium marker increase its ability to be detected by an X-ray. (*see, e.g.*, Dyer, US Pat. No. 4,639,253, col. 3, lines 4-12).

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Additionally, making all three of the markers the same spherical shape would simplify the manufacturing process, e.g., would not have to tool up for different shapes.

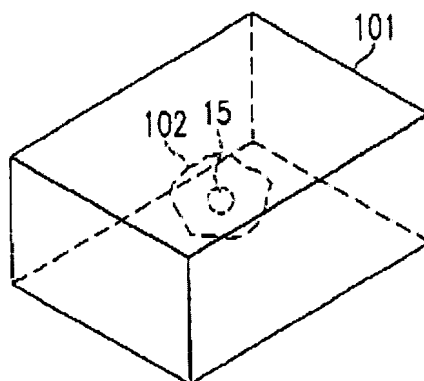
At the time of the invention, it would have been obvious to one of ordinary skill in the art to maximize the size and/or density of a radiopaque marker in the cavity marking device of Sirimanne in order make it more readily detectable by an X-ray.

Regarding claim 17, Sirimanne teaches that the three markers (150, 154, 156) are contiguous (see figure 1D, supra). As interpreted herein, “contiguous” is construed as being neighboring or adjacent. See definitions of contiguous provided by *Encarta* ([http://encarta.msn.com/dictionary\\_1861599914/contiguous.html](http://encarta.msn.com/dictionary_1861599914/contiguous.html)) and *The Free Dictionary by Farlex* (<http://www.thefreedictionary.com/contiguous>). The words of a claim must be given their “plain meaning” unless such meaning is inconsistent with the specification. MPEP § 2111.01. Applicants’ specification does not provide a definition of “contiguous” that is contrary to elements that are neighboring or adjacent.

Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne as applied to claims 1-7 above, and further in view of Ishikawa *et al.* (US 6,366,206 B1; hereinafter “Ishikawa”).

Sirimanne does not teach an electronic tag.

Ishikawa teaches a surgical sponge (101) with an electric transponder (15)(see fig. 7, below).

**FIG. 7**

At the time of the invention, it would have been obvious to add the electronic transponder of Ishikawa to the surgical sponge of Sirimanne in order to provide a remote means of tracking the sponge (abstract; col. 8, lines 42-51).

Claims 13, 14, 18 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne as applied to claims 1-7 above, and further in view of *Uncommon Peril of Forgotten Surgical Tools*, Davis Grady, The New York Times, Jan. 21, 2003 (hereinafter "*Uncommon Peril*").

Sirimanne does not disclose expressly the steps of x-raying a patient and removing a surgical sponge thereafter.

*Uncommon Peril* teaches that a patient suspected of having a surgical sponge or other implement having a marker inside them can be x-rayed and if the implement is found to be there, it can be removed.

Regarding claim 18 and 19, Sirimanne teaches that the three markers (150, 154, 156) are contiguous (see figure 1D, supra). As interpreted herein, "contiguous" is construed as being neighboring or adjacent.

***Response to Arguments***

Applicant's arguments filed 05 March 2007 have been fully considered but they are not persuasive.

Applicants assert that new claims 17-19 add the limitation such that the radiopaque markers are contiguous, which distinguishes them from the applied art. This argument is not persuasive because, as described supra, contiguous is interpreted herein as being synonymous with adjacent or neighboring. Sirimanne teaches markers that are neighboring or adjacent each other, even if they do not directly touch one another.

Applicants assert that Sirimanne does not disclose or suggest a surgical sponge with three spherical radiopaque markers being closely grouped. This argument is not persuasive because Sirimanne suggests modifying the markers shapes with a wide variety of possibilities so long as they are readily detectable by x-ray equipment (col. 7, lines 1-25). Using only one type of marker shape would reduce manufacturing complexity. As far as the markers being closely grouped together, this is a relative limitation and applicants have not provided a definition that precludes interpreting the references markers as being closely grouped to one another.

Applicants assert that Sirimanne teaches away from a sponge with three spherical sponges. This argument is not persuasive because Sirimanne shows an embodiment that only uses a spherical marker, yet manages to be suitable for use in detecting the sponge (fig. 1A). Furthermore, adding two additional spherical markers to the embodiment shown in fig. 1D would enhance the overall marker footprint while maintaining the benefits of the other shapes.

Applicants assert that it would have not been obvious to combine the two types of markers/tags in a single sponge. This argument is not persuasive because Sirimanne teaches the use of an electronic identifying tag (170) with a marker (150)(fig. 2F).

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

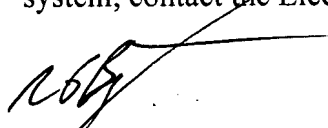
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart  
23 May 2007

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

